

# INSTRUCTIONS FOR USE VOICE CONTROL for SOLOASSIST

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## 1 Introduction

Please read this instructions for use to learn about the correct use of the VOICE CONTROL before using it for the first time.

Keep the instructions for use close to the site of operation and ensure that the user can access it at all times.

	Never use the VOICE CONTROL in the OR without having been instructed by an authorised person in its safe use.
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### 1.1 Purpose of the document

This document tells you how to handle the VOICE CONTROL for SOLOASSIST. In conjunction with the instructions by our trained specialists, it allows you to safely handle the VOICE CONTROL for SOLOASSIST.


This document has been created for anyone put in charge with the setup, operation and cleaning of the device.

### 1.2 Notes on this document

*Notes to avoid damage to property:*

	This symbol is found in front of notes to assist the user, to facilitate the use of the device or to prevent faults.
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*Safety information to avoid risk of injury:*





	This symbol indicates safety information. Non-compliance with the corresponding information may lead to damage or even injuries for the patients and / or the user.
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Words written in CAPITAL LETTERS indicate parts or accessories of the system as well as important terms regarding their use.






### 1.3 Important notes on the safe handling (summary)

The incorrect operation or non-compliance with precautionary measures may cause serious incidents, injuries of patients or damage to persons or material.

Therefore, use this instruction manual to fully inform yourself about the correct operation and handling of the VOICE CONTROL for SOLOASSIST.

	The VOICE CONTROL is designed exclusively for use with the SOLOASSIST camera guidance system. Do not use it with other devices.
	Observe all safety instructions in this instructions for use as well as the instructions for use for the SOLOASSIST.
	The device is not intended for the operation in explosive areas. Ensure a sufficient distance to highly flammable gases (e.g. O <sub>2</sub> , anaesthetic gases).
	Never open the device. Risk of an electric shock!

	The VOICE CONTROL is a device of protection class I. Only connect the VOICE CONTROL to a power outlet with a protective earth conductor.
	Unplug this unit from the power supply to disconnect it completely from the mains. Make sure that the mains connection is accessible at all times. The mains plug is considered to be the disconnecting device from the mains.
	Devices that are connected to the analogue and digital interfaces of the VOICE CONTROL must comply with the standards for electromedical devices. All configurations must meet the requirements of the system standard EN 60601-1. The person connecting additional devices is responsible for the compliance with this standard!
	Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the VOICE CONTROL, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
	Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
	The VOICE CONTROL may not be placed directly adjacent to other equipment or stacked with other equipment. If it is necessary to operate the device close to other equipment and stacked with other equipment, the VOICE CONTROL should be monitored in order to check the proper operation with this arrangement.
	Only use the original HEADSET that was delivered with the VOICE CONTROL or that you have obtained as spare part from AKTORMed or an authorised dealer.
	All serious incidents related to the product must be reported to the manufacturer and the competent authority in the country concerned.
	Avoid tripping hazards when connecting the cables.
	Modifications to the device are not permitted! Warranty seals are attached to the housing of the VOICE CONTROL, which indicate unauthorised opening of the VOICE CONTROL. If you notice a damaged warranty seal, check the functionality of the VOICE CONTROL before using it. If you still have doubts about the proper condition of the device, please contact the AKTORMed Service or the respective service partner.
	MEDICAL ELECTRICAL DEVICES are subject to special EMC precautions. The VOICE CONTROL may only be installed and commissioned in accordance with the EMC instructions contained in this manual.
	Portable and mobile HF communication devices such as cell phones can interfere with MEDICAL ELECTRICAL DEVICES. Do not operate such devices in the direct vicinity of the VOICE CONTROL.
	Operate the VOICE CONTROL only when it has reached room temperature again after a previous storage at high or low temperatures.

	If there is a power failure or if the unit is accidentally switched off during use, all stored values are lost and must be reset.
	Wait a few seconds after switching off the device before restarting the VOICE CONTROL.
	Do not press the power switch again while the VOICE CONTROL is still shutting down.
	The connected SOLOASSIST system must have a software version 2.0 or higher to use the VOICE CONTROL. Contact your dealer or AKTORMed directly to obtain a software update.
	The national regulations are to be complied when the product or its components are disposed of or recycled.

## 1.4 Modifications

Subject to technical modifications!

Both the device and the instructions for use are developed and improved on a continuous basis. Some illustrations may therefore slightly differ from the actual delivery condition.

These instructions for use have been prepared with the utmost care. We are not liable for mistakes and printing errors!

Your improvement suggestions in regard to our products or these instructions for use are always welcome. Please contact the address provided in this instructions for use or your competent sales partner.

## 1.5 General product description

The VOICE CONTROL is an optional input device for the SOLOASSIST. It enables the surgeon to control the SOLOASSIST and thus the position of the endoscope with simple commands via speech. There is no need for user training or language training.

In addition, up to three endoscope positions can be stored and recalled, and the speed of movement of the SOLOASSIST can be set in three stages.

The VOICE CONTROL can be used either as a stand-alone input device or in parallel with a connected JOYSTICK or REMOTE CONTROL.

The product works with software. You can find out more in document 1515-240319 (Cybersecurity label – Soloassist), which is available on request.

## 1.6 Intended use / Notes on product liability

The VOICE CONTROL is an accessory for the SOLOASSIST. Do not use the VOICE CONTROL with other devices.

*Essential Performance:*

### Recording and processing voice commands

The system records spoken commands from the user via a HEADSET and uses them to form driving commands for the SOLOASSIST.

### Saving positions

The system can store camera positions and allows the user to recall them.

*Environment:*

Operating room. Ideally, the VOICE CONTROL for SOLOASSIST is placed in the endoscopy tower.

During HF Surgery, the SOLOASSIST and VOICE CONTROL is only compatible with following HF SURGICAL EQUIPMENT:

Power Cut mode capability of 300 W, working frequencies to include at least 400 kHz  $\pm$  100 kHz;

Coagulation mode capability of 100 W, working frequencies to include at least 400 kHz  $\pm$  100 kHz;

The SOLOASSTIST and VOICE CONTROL can not be used for argon plasma coagulation mode.



The device is not intended for the operation in explosive areas. Ensure a sufficient distance to highly flammable gases (e.g. O<sub>2</sub>, anaesthetic gases).

*User Group:*

A mandatory requirement for using the VOICE CONTROL is the proper assembly and maintenance of the device as well the compliance with this instruction manual.

The VOICE CONTROL is used primarily by the surgeon performing the operation. He must have sufficient experience in the use of minimally invasive operating techniques and received instructions in the handling of the VOICE CONTROL.

*Application:*

Input of voice commands for controlling the SOLOASSIST.

*Contraindications:*

The restrictions on the use of the SOLOASSIST apply.

The manufacturer will only consider himself liable for the safety-related characteristics, reliability and performance if

- the user has been fully instructed in the proper use of the device.
- the assembly, readjustments, modifications or repairs are performed exclusively by the manufacturer or an institution expressly authorised by the manufacturer.

- the device is used under the specified environmental conditions in rooms used for medical purposes in which the electrical installation meets the requirements of the VDE 0100-710 or IEC 60364-7-10 standard.
- the device is used entirely in accordance with this instruction manual.

#### *Warranty:*

The manufacturer issues a 12 month warranty on the performance of the product. The period of validity of this warranty is limited to claims that have been immediately asserted in writing within the named period after the invoice date - if applicable, with a reference to repairs stating the invoice number. Legal warranty claims are not restricted by this warranty.

If you did not purchase the product directly from the manufacturer, please contact your sales partner for the processing of the warranty.

This warranty covers only defects that have not been caused by normal wear, misuse, improper handling, external influences, deficient or incorrect preparations, or force majeure.

All warranty claims will be lost if the user itself or a non-authorized repair shop has carried out repairs or modifications on the product.

Liability claims arising from the improper use or from a combination with other devices or accessories can not be asserted.

## **1.7 Receiving inspection**

Please check the VOICE CONTROL and the enclosed accessories immediately upon receipt for possible transport damage and defects.

Claims for damages can be asserted only if the seller or the freight forwarder is immediately informed. A damage report has to be prepared immediately. The damage report must be submitted directly to the manufacturer or the sales partner of the manufacturer so that the claims for damages can be reported to the insurance company.

When a device is returned to the manufacturer, use, if possible, the original packaging. The following accompanying documents are to be enclosed: Name and address of the owner, ID and serial number (see name plate) as well as a description of the defect.

## **1.8 Initial operation**

The operator may operate the VOICE CONTROL only after the manufacturer or the supplier:

- has performed a functional test of the devices at the place of operation and
- has instructed the persons responsible for the operation in the proper handling of the VOICE CONTROL for SOLOASSIST based on this instruction manual.



Operate the VOICE CONTROL only when it has reached room temperature again after a previous storage at high or low temperatures.






#### Location of the Bluetooth Dongle:

The Bluetooth dongle for the HEADSET is located under the protective cap on the back of the VOICE CONTROL. The protective cap ensures a secure connection and prevents the Bluetooth dongle from being unplugged and replaced with another USB device. Further information can be found in document no. 1515-240319 (Cybersecurity label – Soloassist).



fig. 1: Bluetooth dongle for the HEADSET

	<p>Modifications to the device are not permitted!</p> <p>Warranty seals are attached to the housing of the VOICE CONTROL, which indicate unauthorised opening of the VOICE CONTROL. If you notice a damaged warranty seal, check the functionality of the VOICE CONTROL before using it. If you still have doubts about the proper condition of the device, please contact the AKTORMed Service or the respective service partner.</p>
	<p>The supplied dongle has already been paired with the HEADSET. Make sure not to swap the HEADSET with another VOICE CONTROL.</p>
	<p>Only use the original HEADSET that was delivered with the VOICE CONTROL or that you have obtained as spare part from AKTORMed or an authorised dealer.</p>

## 2 System Description

### 2.1 Overview



fig. 2: Overview

Number	Description
1	Connection SOLOASSIST
2	Display „Ready“
3	Display „Connected“
4	Display „HEADSET“
5	Display „Voice input active“
6	Display „Speed“
7	On/off switch
8	Connection supply cable and fuses
9	Bluetooth Dongle for the HEADSET

Table 1: Overview

## 2.2 System components





Component	Picture	Description
VOICE CONTROL  (multiple patient multiple use)		The VOICE CONTROL evaluates the spoken commands of the user and transmits them to the SOLOASSIST.  Ideally, the VOICE CONTROL is placed in the endoscopy tower.
HEADSET with charging station  (multiple patient multiple use)		The HEADSET is worn by the user and records the voice commands. The HEADSET can be stored in the charging station and charged for the next use.  The charging station can be set up independently from the VOICE CONTROL.
CONNECTION CABLE  (multiple patient multiple use)		The CONNECTION CABLE connects the SOLOASSIST with the VOICE CONTROL.  The total length is 3500 mm.
Y-LINE  (multiple patient multiple use)		The Y-LINE allows simultaneous connection of the VOICE CONTROL and a JOYSTICK or a REMOTE CONTROL to the SOLOASSIST.  The total length is 300 mm.

Table 2: System components

#### Overview accessories and spare parts:

For orders, please contact the manufacturer or your sales partner directly.

Only use original accessories. The use of accessories not approved by the manufacturer can lead to a patient hazard or damage to the device.

Article number	Article name	Description
171894	VOICE CONTROL	VOICE CONTROL
171882	HEADSET	HEADSET with charging station
172039	CHARGER HEADSET	CHARGER HEADSET
171896	CONNECTION CABLE	CONNECTION CABLE
171895	Y-LINE	Y-LINE
1515-170066	Manual VOICE CONTROL – EN	-
1206-140108	Manual SOLOASSIST II – EN	-
1828-190039	Manual SOLOASSIST IIS – EN	-

Table 3: Article numbers

## 2.3 Mechanical data

### VOICE CONTROL





Weight	2,8 kg
Dimensions (W x H x D)	350 x 80 x 250 mm
Type of enclosure	IP20

### HEADSET

Type	Sennheiser MB Pro 1 UC ML, including BTD 800 USB ML
Mode of wear	Single-sided head band
Technology	Bluetooth® Version 4.0 supported profiles: HSP 1.2 + HFP 1.6 + A2DP 1.2
Speaking time	Up to 15 h
Standby time	Up to 450 h
Charging time	2 h 30 min
Charging time for 50%	40 min
Reach	Up to 25 m (depending on environment)
Weight	63 g
Type of modulation	GFSK
Bandwidth	1 MHz


## 2.4 Electrical data

Input voltage	100 - 240V~; 47-63Hz
Max. power consumption	60W
Safety Class	I
Mode	continuous
Mains fuses	2x T1A – 5x20 mm

	<p>Devices that are connected to the analogue and digital interfaces of the VOICE CONTROL must comply with the standards for electromedical devices.</p> <p>All configurations must meet the requirements of the system standard EN 60601-1. The person connecting additional devices is responsible for the compliance with this standard!</p>
	<p>Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.</p>
	<p>Unplug this unit from the power supply to disconnect it completely from the mains. Make sure that the mains connection is accessible at all times. The mains plug is considered to be the disconnecting device from the mains.</p>
	<p>The VOICE CONTROL is a device of protection class I. Only connect the VOICE CONTROL to a power outlet with a protective earth conductor.</p>

#### HEADSET

Transmission frequency HEADSET	2.402 MHz to 2.480 MHz
Output power HEADSET	9 dBm / 7,90 mW
Output power Dongle	8 dBm / 6,30 mW
Frequency range Dongle	2.402 MHz bis 2.480 MHz
Microphone type	Ultra noise-cancelling
Frequency range	150 Hz to 6.800 Hz
Loudspeaker type	Dynamic, neodymium magnet
Frequency range	150 to 15.000 Hz
Sound pressure	Max. 118dB (SPL) limited by ActiveGuard (® Sennheiser)

	<p>Portable and mobile HF communication devices such as cell phones can interfere with MEDICAL ELECTRICAL DEVICES. Do not operate such devices in the direct vicinity of the VOICE CONTROL.</p>
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## 2.5 Environmental conditions

#### *for transport and storage*


Temperature	-20°C to +60°C
Relative air humidity	10% to 90%, non-condensing
Air pressure	700 hPa to 1060 hPa

#### *for the operation*

Temperature	+15°C to +37°C
Relative air humidity	20% to 85%, non-condensing
Air pressure	700 hPa to 1060 hPa

## 2.6 Storage and transport

The VOICE CONTROL must always be transported in a suitable packaging. Any position is possible during transportation.

	Operate the VOICE CONTROL only when it has reached room temperature again after a previous storage at high or low temperatures.
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## 2.7 Symbols used on the name plates / labels











Symbol	Description
	Observe the instructions for use
	Follow the instructions for use
	Device conforms to the regulation MDR - 2017/745 (Medical Device Regulation)
	Date of manufacture
	Manufacturer
	Serial number
	Reference number
Rx only	Sale only on instruction of a physician (US federal law)
	Authorised representative in Switzerland
	Medical Device
	Dispose products marked with this symbol separately with electric and electronic devices. The disposal is carried out by the manufacturer within the EU for free.

Table 4: Symbols on nameplate and label

## 2.8 Application parts

In terms of the 60601 standard, the VOICE CONTROL has no application parts that have contact with the patient when used as intended.

## 2.9 Name plate

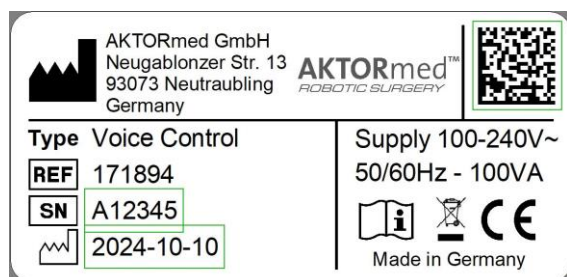


fig. 3: Name plate

## 2.10 Identification according to MDR (Medical Device Regulation)

The VOICE CONTROL for SOLOASSIST is as an accessory of a class I medical device also a class I medical device.

## 2.11 Contact

If you have any further questions in connection with the product, please contact:

AKTORMed GmbH  
 Neugablonzer Str. 13  
 93073 Neutraubling  
 GERMANY

Web: [www.aktormed.com](http://www.aktormed.com)  
 eMail: [info@aktormed.com](mailto:info@aktormed.com)  
 Phone: +49 9401 93 20 110



### 3 Setup / Commissioning

The VOICE CONTROL for SOLOASSIST is ideally located in the equipment tower.

#### *Step 1: Establish the electrical connection*



Connect the supply line to the VOICE CONTROL and then plug the supply line into a suitable power outlet.

Connect the charging station of the HEADSET to a suitable power outlet.

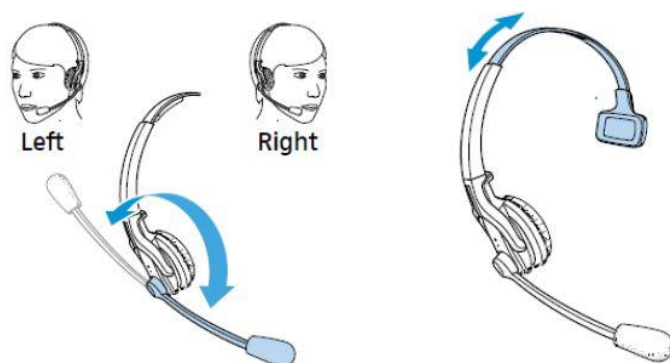
	Unplug this unit from the power supply to disconnect it completely from the mains. Make sure that the mains connection is accessible at all times. The mains plug is considered to be the disconnecting device from the mains.
	Avoid tripping hazards when connecting the cables.

#### *Step 2: Connect HEADSET and wear*

The HEADSET communicates with the VOICE CONTROL via a Bluetooth connection. For this purpose a Bluetooth dongle is plugged into the back of the VOICE CONTROL. The connection to the HEADSET is then automatically established when the VOICE CONTROL is started.

	Never remove the Bluetooth dongle from the VOICE CONTROL.
	Only use the original HEADSET that was delivered with the VOICE CONTROL or that you have obtained as spare part from AKTORMed or an authorised dealer.

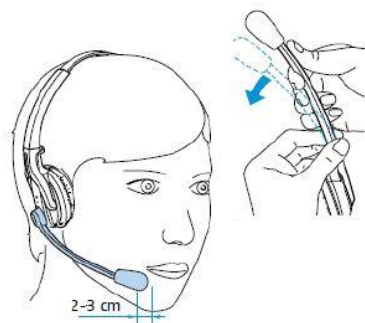
The HEADSET can be worn with the speaker on the left or right ear. To do this, swivel the microphone boom in the appropriate direction. The length of the retaining strap can be adjusted as required.



*fig. 4: Customise HEADSET*



Adjust the microphone boom so that the microphone is about 2-3 cm from the corner of your mouth.

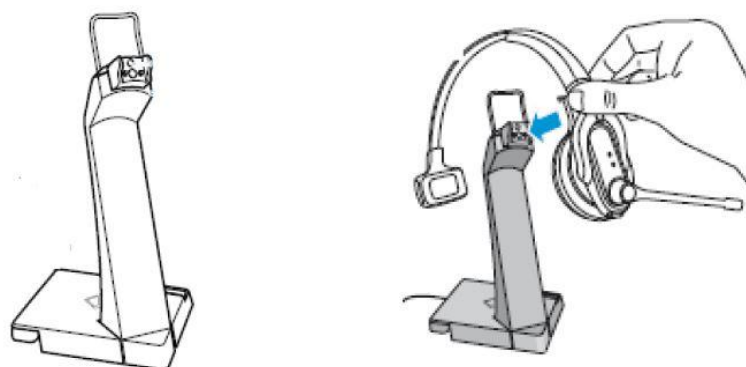


*fig. 5: Adjust microphone boom*

For details on how to use the HEADSET, please refer to the supplied user manual of the HEADSET.

### *Step 3: Charge HEADSET*

Place the HEADSET in the receptacle of the charging station for safe storage and charging.



*fig. 6: Charging HEADSET*

*Step 4: Connecting SOLOASSIST to VOICE CONTROL*

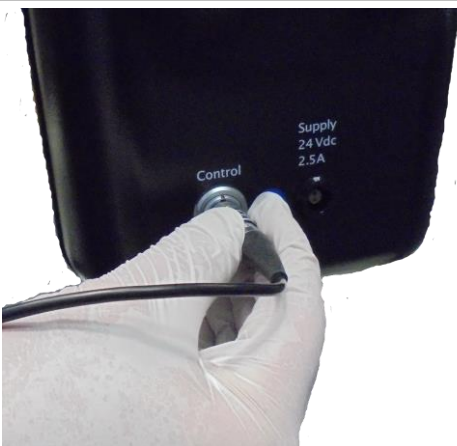
Picture	Description
	Connect the CONNECTION CABLE to the CONTROL jack on the SOLOASSIST.
	Connect the other end of the CONNECTION CABLE to the VOICE CONTROL jack.

*Table 5: Connecting the SOLOASSIST to the VOICE CONTROL*



The connected SOLOASSIST system must have a software version 2.0 or higher to use the VOICE CONTROL. Contact your dealer or AKTORMed directly to obtain a software update.

*Step 5 (optional): Connecting an additional JOYSTICK or REMOTE CONTROL*

Picture	Description
	Instead of the CONNECTION CABLE, connect the Y-LINE to the CONTROL jack of the SOLOASSIST.



*Table 6: Option additional joystick*

Connect the CONNECTION CABLE to a socket on the Y-LINE.

Connect JOYSTICK or REMOTE CONTROL to the other socket of the Y-LINE.

The use of the JOYSTICK is generally described in the SOLOASSIST instruction manual, and in particular in the JOYSTICK instruction manual.



If VOICE CONTROL and JOYSTICK or REMOTE CONTROL are used simultaneously, movement will be stopped in case of conflicting inputs (e.g. left with the JOYSTICK, right with the VOICE CONTROL).

## 4 Operation

VOICE CONTROL for SOLOASSIST is controlled by voice input at the HEADSET. The HEADSET is wireless and is worn by the surgeon.

After the VOICE CONTROL has been connected to the mains, it is in standby mode. The power switch is orange.



Display	Symbol	Colour	Meaning
Standby		Orange	The VOICE CONTROL is powered but not started.
ON		Green	The VOICE CONTROL is switched on.

Table 7: Switch on VOICE CONTROL

### Switch ON

Briefly press the power switch to start the VOICE CONTROL. The power switch will light green.

The start process of the VOICE CONTROL usually takes about one (1) minute. During this time, only the green power switch lights up. After the successful start of the VOICE CONTROL, further operating elements light up.

### Switch OFF

Briefly press the power button to turn off the VOICE CONTROL. The power switch will remain green for a few seconds. After successful completion of the software, the VOICE CONTROL is in standby mode again. The power switch will light orange.



Do not press the power switch again while the VOICE CONTROL is still shutting down.



Wait a few seconds after switching off the device before restarting the VOICE CONTROL.

### Status displays








Display	Symbol	Colour	Meaning
Speed		Green	Displays the chosen speed in terms of three levels.
Ready		Green	Is lit once VOICE CONTROL has been started successfully.
Connected		Green	Is lit once VOICE CONTROL has been connected to a SOLOASSIST successfully.
HEADSET		Green	Is lit if the dongle of the HEADSET has been recognised
Voice input		Green	The voice input field lights up green when the keyword "SOLO" is recognized. The system is then ready to execute voice commands. This field flashes green during a software update.

Table 8: Status indications

	A green "HEADSET" indicator does not automatically mean that a connection to the HEADSET exists.
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## 4.1 Voice Commands

The Voice Command Set allows precise control over the positioning of the endoscope during surgery. Each command sequence starts with the keyword "SOLO". Once this keyword has been recognized, commands are accepted within 10 seconds. During this period, the "Voice input" indicator lights green.

Display status	Description
	The VOICE CONTROL waits for the keyword "SOLO" and is in standby mode.


	<p>The keyword has been recognized, the VOICE CONTROL is now ready to accept commands, which are then executed by the SOLOASSIST.</p> <p>10 seconds after the last detected command, the VOICE CONTROL returns to standby mode.</p>
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Table 9: Activate VOICE CONTROL

If no command is detected within this period, the VOICE CONTROL will return to standby mode and wait for the keyword "SOLO" to be renamed again. If a correct command is detected, the period restarts, which means that successive commands can be given without renaming the keyword "SOLO". All command words are expected in English.

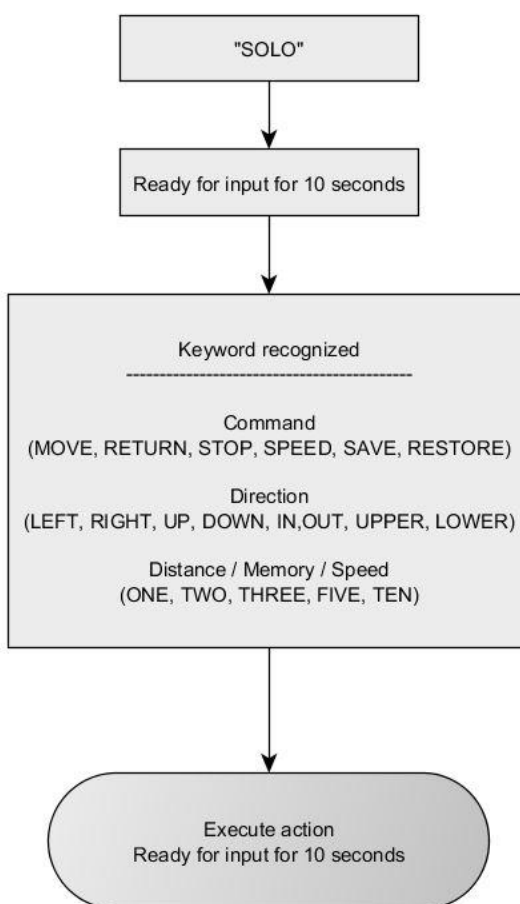


fig. 7: Flowchart voice input

### 4.1.1 Motion Commands

A motion command consists of direction (LEFT, RIGHT, UP, DOWN) or zoom (IN, OUT), and distance (ONE, TWO, THREE, FIVE, TEN). The direction can be modified to 45° with the command words UPPER and LOWER. The keyword MOVE repeats the last movement.

All directions refer to the monitor image. Pay attention to the anatomically correct adjustment of the image horizon.

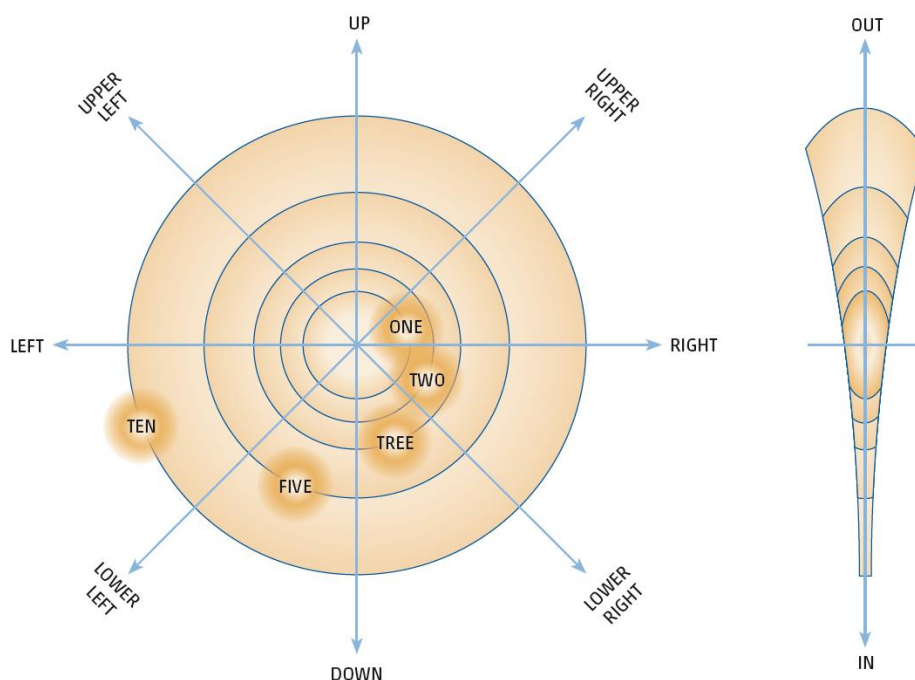


fig. 8: Motion Commands

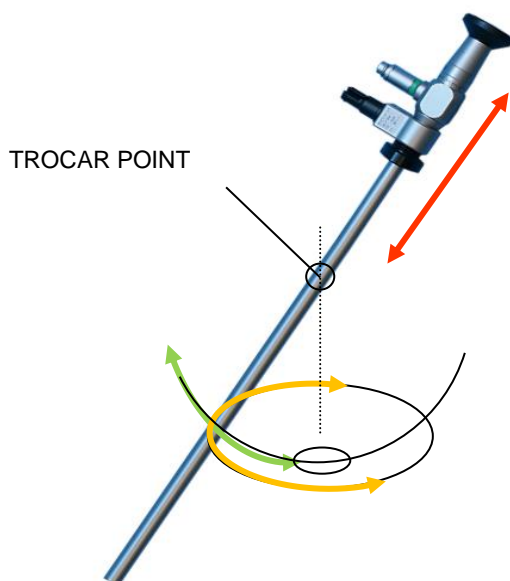
Desired image change	Required command
Image to the right	ONE RIGHT
Image to the left	ONE LEFT
Image up	ONE UP
Image down	ONE DOWN
Image 45° upwards to the right	ONE UPPER RIGHT
Image 45° upwards to the left	ONE UPPER LEFT
Image 45° downwards to the right	ONE LOWER RIGHT
Image 45° downwards to the left	ONE LOWER LEFT
Overview	ONE OUT
Detail view	ONE IN
Repeat movement	MOVE

Table 10: Motion commands



The keyword ONE in the table above is an example of the distance. This executes the minimum movement step. The procedure for the further movement steps (TWO, THREE, FIVE, TEN) must be used in the same way.

*Corresponding movements of the endoscope within the trocar*



*fig. 9: Endoscope movement*

#### **4.1.2 Store and recall positions**

The key words SAVE and RESTORE, followed by ONE, TWO or THREE can be used to save and to restore, if required, up to three positions. The key word RETURN is used to undo the last movement.

#### **4.1.3 Set speed**

The key word SPEED, followed by ONE, TWO or THREE can be used to adjust the speed of movements of SOLOASSIST to three preset speed levels.

#### 4.1.4 Cancel movement

##### *Via voice input*

A movement can be stopped at any time by entering the key word "STOP", even if voice input is not active (display box "Voice input" is not lit). As long as voice input is active, a movement can be interrupted by entering any key word.

##### *Via manual movement*

A movement is interrupted once the unlock button of SOLOASSIST (see SOLOASSIST manual) is actuated.

##### *Emergency stop*

Pressing the emergency stop button on the SOLOASSIST interrupts the power supply to the motors. Thus, all movements are stopped. However, the SOLOASSIST can continue to be moved by hand at any time.



If a joystick is simultaneously connected to the SOLOASSIST, the movement also stops if a button on the joystick is pressed during a movement.

## 4.2 Cleaning / wipe disinfection

The VOICE CONTROL can be cleaned by wiping with a soft damp, non-wet cloth.

The VOICE CONTROL has been successfully proved due to surface resistance against disinfecting agents:

disinfectant	agent	mass concentration in 100 g solution:
Microbac (cloths)	Benzyl-C12-18-Alkyldimethylammoniumchlorid	0,4 g
	Didecyldimethylammoniumchlorid	0,4 g
Meliseptol HBV (cloths)	1-Propanol	50 g
	Didecyldimethylammoniumchlorid	0,075 g
Incidin Liquid	2-Propanol	35 g
	1-Propanol	25 g
Isopropanol	2-Propanol	63,1 g

Table 11: Disinfecting agents



You can proceed the wipe disinfection by using the named disinfectants or using disinfectants with similar disinfecting agents.

Apply the disinfectants by using a soft cloth and consider the instructions of the manufacturer of the disinfectant concerning the application time.



## 5 Troubleshooting

In case VOICE CONTROL for SOLOASSIST does not behave as expected, the following information is intended to help you resolve straightforward problems yourself.

	Never open the device. Risk of an electric shock!
	<p>Always contact the manufacturer's service or a representative expressly authorised by the manufacturer:</p> <ul style="list-style-type: none"> <li>• if you are not able to solve the problem with the help of the following information or</li> <li>• if safe work is no longer ensured.</li> </ul>

Symptom	Solutions
The power button of the VOICE CONTROL lights up green, otherwise no display and no function	<p>The VOICE CONTROL was not started successfully. Press and hold the Power button for at least five (5) seconds to turn off the VOICE CONTROL.</p> <p>Wait at least ten (10) seconds and restart the VOICE CONTROL.</p>
The "HEADSET" indicator lights up, but no commands are detected	<p>Check the state of charge of the HEADSET.</p> <p>Restart the VOICE CONTROL. Make sure that the dongle of the HEADSET is connected.</p>
The "Connected" indicator does not light	Check the cable connection to the SOLOASSIST.
The "Voice input" display flashes	A software update is performed. When the update is complete, remove any USB stick that may be connected.

Table 12: Troubleshooting

## 6 Service

VOICE CONTROL for SOLOASSIST does not require any maintenance on principle. To ensure safe operation over the duration of its service life, however, regular checks and safety inspections are essential.

### 6.1 Handover certificate

The manufacturer or a representative expressly authorized by the manufacturer will commission the device upon delivery.

### 6.2 Regular inspections

Perform the following checks before each use of the device:

- Check power cord for damage
- Check VOICE CONTROL and accessories for signs of external damage



Never use the VOICE CONTROL for SOLOASSIST if you can see any damage. Call the service responsible for you.

### 6.3 Annual safety-related inspection

A regular maintenance is not required. However, the manufacturer requires a specialist or a hospital technician to carry out a precautionary safety inspection on a regular basis in order to ensure a reliable operation over its lifetime. This inspection must be carried out at least once a year.

No special requirements or precautions have to be considered for a precautionary inspection. During the inspection, the following tests have to be performed in accordance with section 5 of the DIN EN 62353:

- 5.2 Inspection
- 5.3.2 Measurement of the protective conductor resistance, where applicable
- 5.3.3 Measurement of the leakage currents
- 5.3.4 Measurement of the insulation resistance

The test results are to be fully documented in a test report according to section 6 of the DIN EN 62353. The test report can be taken from section F of the standard.

In case of a malfunction, please contact the AKTORMed Service or the respective service partner. In addition to an accurate description of the error, please also always indicate the product identification number and serial number as shown on the name plate of the device.



All serious incidents related to the product must be reported to the manufacturer and the competent authority in the country concerned.

## 6.4 Disposal / Recycling

The manufacturers confirm that the product

VOICE CONTROL for SOLOASSIST

complies with the following Directives:




- Waste electrical and electronic equipment (WEEE) 2012/19/EC,
- Electrical and Electronic Equipment Act - ElektroG in Germany,
- and the legal requirements of the EEA member states.

Further information can be found in document no. 1515-190114 (Recycling pass Voice Control).



The national regulations are to be complied when the product or its components are disposed of or recycled.

## 7 EMC

	MEDICAL ELECTRICAL DEVICES are subject to special EMC precautions. The VOICE CONTROL may only be installed and commissioned in accordance with the EMC instructions contained in this manual.
	Portable and mobile HF communication devices such as cell phones can interfere with MEDICAL ELECTRICAL DEVICES. Do not operate such devices in the direct vicinity of the VOICE CONTROL.
	The VOICE CONTROL may not be placed directly adjacent to other equipment or stacked with other equipment. If it is necessary to operate the device close to other equipment and stacked with other equipment, the VOICE CONTROL should be monitored in order to check the proper operation with this arrangement.

### Guidelines and manufacturer's declaration - Electromagnetic emissions

#### Emission

Test	Limit	Electromagnetic environment - guidance
Conducted emission	CISPR 11, Group 1, Class B	Device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiated emission	CISPR 11, Group 1, Class B	
Voltage fluctuations and flicker	IEC 61000-3-3	Device is directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.  Only for Home healthcare environment.

Table 13: Emission

#### Immunity test levels

Test	Limit	Electromagnetic environment - guidance
Electrostatic Discharge (IEC 61000-4-2)	Contact Discharge: $\pm 8$ kV Air Discharge: $\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV, $\pm 15$ kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF EM field (IEC 61000-4-3)	80-2700 MHz; 1kHz AM 80 %; 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance:</b> $d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 800 MHz to 2,7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter

Test	Limit	Electromagnetic environment - guidance
		manufacturer and d is the recommended separation distance in meters (m).
Proximity fields from RF wireless communications equipment (IEC 61000-4-3)	385 MHz; Pulse Modulation: 18 Hz; 27 V/m 450 MHz, Pulse Modulation: 18 Hz; 1 kHz sine; 28 V/m 710, 745, 780 MHz; Pulse Modulation: 217 Hz; 9 V/m 810, 870, 930 MHz; Pulse Modulation: 18 Hz; 28 V/m 1720, 1845, 1970 MHz; Pulse Modulation: 217 Hz; 28 V/m 2450 MHz; Pulse Modulation: 217 Hz; 28 V/m; 5240, 5500, 5785 MHz; Pulse Modulation: 217 Hz; 9 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance 30 cm.
Electrical fast transients / bursts (IEC 61000-4-4)	Power lines: 2 kV; 100 kHz repetition frequency Signal lines: 1 kV; 100 kHz repetition frequency	Mains power quality should be that of a typical environment.
Surges (IEC 61000-4-5)	L-N: 1kV at 0°, 90°, 180°, 270° L-PE & N-PE: 2kV	Mains power quality should be that of a typical environment.
Conducted disturbances induced by RF fields (IEC 61000-4-6)	0.15-80 MHz; 1kHz AM 80 %; 3 Vrms , 6 Vrms in ISM band	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. <b>Recommended separation distance:</b> $d = 1.2\sqrt{P}$ for 150 kHz to 80MHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Rated power frequency magnetic fields (IEC 61000-4-8)	30 A/m, 50 Hz and 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips / Voltage interruptions (IEC 61000-4-11)	0 % UT for 0.5 cycle at 8 phase angles 0 % UT for 1 cycle at 0° 70 % UT for 25/30 cycles at 0° 0 % UT for 250/300 cycles 0°	Mains power quality should be that of a typical environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device is powered from an uninterruptible power supply or battery.

Table 14: Immunity test level



	<p>Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.</p>
	<p>Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the VOICE CONTROL, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.</p>

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